Abstract: 787

Diagnostic Accuracy of Cepheid GeneXpert HIV-1 Qual for Early Infant Diagnosis

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BACKGROUND

- Among HIV-exposed infants, delays in early infant diagnosis (EID) result in high morbidity and mortality. The World Health Organization (WHO) recommends HIV PCR testing of HIV-exposed infants at 6 weeks for EID.
- In many resource-limited settings, testing is available only in centralized laboratories, resulting in delays in diagnosis.
- Cepheid GeneXpert is a polyvalent platform suitable for use near point-of-care (Figure 1).
- Cepheid recently released GeneXpert HIV-1 Qual (Xpert). The use of Xpert for EID in decentralized settings, could reduce delays in EID and ART initiation among infants infected with HIV. The diagnostic accuracy of Xpert HIV-1 Qual was evaluated in the National Microbiology Reference Laboratory (NMRL) in Harare, Zimbabwe.

METHODS

- The study used archived dried blood spot (DBS) samples from HIV-exposed infants and children aged <18 months, that had been sent to NMRL for HIV PCR.
- DBS samples were collected and prepared in health facilities according to standard procedures between January and August 2015.
- Samples were tested within 2 months.
- 428 paired DBS samples were tested using Xpert and Roche Cobas AmpliPrep/Cobas TaqMan (Roche Molecular Diagnostics, CA, USA), with Roche serving as the comparator.
- Samples that were HIV PCR positive on Roche were oversampled in order to enable sensitivity to be evaluated with reasonable precision.
- The technicians who performed the Xpert tests were blind to the Roche test results.

RESULTS

- The median age of infants at testing was 6.9 weeks (interquartile range: 6.1 to 16.1 weeks).
- Of those with information on feeding, 303/389 (77.9%) were breastfed exclusively.
- Of the sample pairs tested, 169/428 (39.5%) were positive on Roche.
- Of the 169 samples that were positive on Roche, 5 (1.2%) were negative on Xpert (Table 1).
- All 259 samples that were negative on Roche were also negative on Xpert.
- The sensitivity of Xpert was 97.0% (95% confidence interval [CI]: 93.2 – 99.0%) and the specificity was 100% (95% CI: 98.6 – 100%).

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<thead>
<tr>
<th>Roche CAP/CTM</th>
<th>Xpert HIV-1 Qual</th>
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<tr>
<td>+</td>
<td>164</td>
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<tr>
<td>–</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>164</td>
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Table 1: Comparison of Xpert Qual and Roche CAP/CTM results

CONCLUSIONS

- Xpert HIV-1 Qual is a promising test for decentralized EID in resource-limited settings.
- Further studies are needed to assess the feasibility and utility of using Xpert HIV-1 Qual for decentralized testing for EID under conditions of intended use.
- Such studies should also assess the feasibility of using GeneXpert as a polyvalent platform for Xpert HIV-Qual and other tests such as Xpert MTB/RIF.

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Figure 1: Cepheid GeneXpert system

Figure 2: Roche COBAS AmpliPrep/COBAS TaqMan 96 ➔

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